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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,315	04/13/2005	Yuki Katayama	00005.001258	6439

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EXAMINER	
WOOD, AMANDA P	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
05/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,315	KATAYAMA ET AL.	
	Examiner	Art Unit	
	AMANDA P. WOOD	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 38-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 38-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response and amendments filed 30 January 2008 has been received and entered.

Claims 1-3 and new claims 38-44 have been examined on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The IDS filed January 30, 2008 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Withdrawn Rejections

In view of Applicant's response and amendments, the rejections of claims 1-3 under 35 U.S.C.102(b) in view of Takayuki et al and in view of Hama et al have been withdrawn. Furthermore, in view of Applicant's amendments to the claims, the rejection of claims 1-5 and 22-26 under 35 U.S.C. 112, second paragraph has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayuki et al and Hama et al in view of Miki et al (US 6,162,607).

Takayuki et al teach a method of measuring HDL-cholesterol in a specimen such as serum or plasma by treating the specimen with a cholesterol esterase and cholesterol oxidase in the presence of albumin separately derived from the specimen. Takayuki et al teach that the specimen is treated with a polyanion such as a sulfated polysaccharide, particularly dextran sulfate, as well as with a nonionic surfactant. Takayuki et al teach that by using peroxidase and a suitably oxidizable color fixative, the amount of hydrogen peroxide generated can be determined. In addition, Takayuki et al teach that cholesterol dehydrogenase may also be used with cholesterol esterase in combination with a coenzyme so as to use well-known methods of detecting reduced enzymes. Furthermore, Takayuki et al teach that PEG, or polyethylene glycol, is used as a nonionic surfactant in the methods of Takayuki et al, although any well-known nonionic surfactants may be used, according to Takayuki et al (see, for example, English abstract, and in English machine-translation version-pg. 6-8).

Hama et al teach a method for specifically assaying HDL cholesterol in which serum or plasma samples having HDL cholesterol are brought into contact with cholesterol esterase, cholesterol oxidase and bile acid or its salt in the presence of albumin and then the compounds consumed or formed by the reactions between the cholesterol and each of the enzymes are measured. In particular, Hama et al teach that having a nonionic surfactant, albumin and bile acid or its salt at a particular

concentration is necessary for reaction to occur with HDL cholesterol specifically (see, for example, English Abstract and pg. 9 of English machine-translation printout).

Takayuki et al and Hama et al do not expressly teach a method wherein the nonionic surfactant is polyoxyethylene alkylamine, polyoxyethylene alkenylamine, or polyoxyethylene polycyclic phenyl ether sulfate.

Miki et al beneficially teach that surfactants for measuring HDL, particularly nonionic surfactants such as polyoxyethylene oleyl ether, in addition to others, preferably those having HLB values of 12 to 17 are useful in reagent solutions which measure HDL cholesterol. Miki et al beneficially teach that those surfactants can be used alone or in combination (see, for example, col. 5, lines 20-60). Furthermore, Miki et al beneficially teach that anionic cholic acid or deoxycholic acid may be used in the reagents in addition to the above nonionic surfactants (see, for example, col. 5, lines 30-55).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Takayuki et al, based upon the beneficial teachings provided by Hama et al, with respect to the art-recognized method of using bile acids or their salts at particular concentrations in combination with nonionic surfactants, cholesterol esterase, cholesterol oxidase, and albumin to measure HDL cholesterol, for the purpose of specifically reacting the enzymes with HDL cholesterol versus other cholesterol, and by Miki et al, with respect to the art-recognized method of using nonionic surfactants having HLB values from 12-17, such as polyoxyethylene oleyl ether, as discussed above. Furthermore, Takayuki et al

particularly point out that any nonionic surfactant may be used in their methods, while Hama et al teach that using bile acids or their salts would be beneficial to use in combination with the nonionic surfactant and enzymes so as to specifically react with the HDL cholesterol compared to the other cholesterols present in a specimen. Furthermore, based upon these beneficial teachings provided by Takayuki et al and Hama et al, and the beneficial teaching provided by Miki et al that nonionic surfactants such as polyoxyethylene oleyl ether and others with HLB values between 12 and 17 are useful for specifically reacting with HDL cholesterol, it would have been both obvious and beneficial for the skilled artisan to use the methods taught by Takayuki et al, Hama et al, and Miki et al so as quantify cholesterol in HDL in a sample. The result-effective adjustment of particular conventional working conditions (e.g., using a particular nonionic surfactant, a particular polyanion, and/or a particular bile acid derivative) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Response to Amendment and Arguments

Applicant's arguments filed 30 January 2008 have been fully considered but they are not persuasive. Applicant argues that the deficiencies of Takayuki et al and Hama et al are not addressed by Miki et al, and that the present invention achieves superior results which are unexpectedly superior over both the primary references.

The Examiner respectfully disagrees with Applicant's arguments because Takayuki et al and Hama et al are specifically cited to show that it was well-known in the art to determine HDL cholesterol in samples by methods using cholesterol esterase and cholesterol oxidase in addition to treating the sample with polyanions, nonionic surfactants, and bile acid derivatives. These references further teach that the amount of cholesterol can be determined by measuring the amount of hydrogen peroxide generated. Miki et al was cited to teach that particular nonionic surfactants, specifically those with a particular HLB value, are useful in reagent solutions to measure HDL cholesterol, and that a particularly useful surfactant is polyoxyethylene oleyl ether.

The declaration under 37 CFR 1.132 filed 30 January 2008 is insufficient to overcome the rejection of claims 1-5 and 38-44 based upon Takayuki et al, Hama et al, and Miki et al, as set forth in the last Office action because: Applicant's declaration does not address the teaching in Miki et al that polyoxyethylene oleyl ether is useful as a nonionic surfactant for determining HDL cholesterol in a sample, which is a particular example given by Applicant in the instant specification of nonionic surfactants (see, for example, page 21, line 6 and page 22, lines 3-4). Miki et al addresses the benefit of using such nonionic surfactants for determining HDL cholesterol. Although it does

appear that Applicant's method using Nymeen L207, or polyoxyethylene dodecylamine, as discussed in the declaration, achieves better correlation of values with the designated comparison method than surfactants used in the prior art, Applicant's argument does not overcome the art of record because Applicant does not address Miki et al's use of polyoxyethylene oleyl ether in the declaration, and furthermore, Applicant does not claim polyoxyethylene dodecylamine in any of the currently pending claims. The currently pending claims still apply to the art of record, and therefore, it would have been both obvious and beneficial for one of skill in the art to provide the claimed method for the express benefit of determining HDL cholesterol in a sample with improved reliability.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA P. WOOD whose telephone number is (571)272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

/Robert B Mondesi/
Primary Examiner, Art Unit 1652
May 1, 2008.